For United Kingdom

Eylea® (aflibercept) 40 mg/mL solution for injection in pre-filled syringe &
Eylea® (aflibercept) 114.3 mg/mL solution for injection in pre-filled syringe

Prescribing Information
(Refer to full Summary of Product Characteristics (SmPCs) before prescribing)

Presentations: Eylea 40 mg/mL: 1 mL solution for injection contains 40 mg aflibercept. Each pre-filled syringe (PFS) contains at least 3.6 mg aflibercept in 0.09 mL solution, providing a usable amount to deliver a single dose of 0.05 mL containing 2 mg aflibercept. **Eylea 114.3 mg/mL:** 1 mL solution for injection contains 114.3 mg aflibercept. Each PFS contains 21 mg aflibercept in 0.184 mL solution, providing a usable amount to deliver a single dose of 0.07 mL containing 8 mg aflibercept. **Indications:** Treatment in adults of neovascular (wet) age-related macular degeneration (nAMD), visual impairment due to diabetic macular oedema (DMO) and visual impairment due to macular oedema secondary to retinal vein occlusion (branch or central RVO). **Posology & method of administration:** Administration by intravitreal injection only, according to medical standards and applicable guidelines by a qualified healthcare professional experienced in administering intravitreal injections. Use a 30 G × ½ inch injection needle. Each PFS should only be used for treatment of a single eye; extraction of multiple doses may increase risk of contamination and infection. Each PFS contains more than the recommended dose. The extractable volume of the PFS is not to be used in full. Expel excess volume and bubbles before injecting. The 8 mg dose requires use of Eylea 114.3 mg/mL PFS with OcuClick dosing system; check label to ensure correct Eylea strength. Refer to SmPC for full details. **Eylea 40 mg/mL:** Recommended dose is 2 mg aflibercept, equivalent to 0.05 mL. *nAMD* Treatment is initiated with 1 injection per month for 3 consecutive doses. Treatment interval is then extended to 2 months. Based on the physician's judgement of visual and/or anatomic outcomes, treatment interval may be maintained at 2 months or further extended using a treat-and-extend (T&E) dosing regimen, where injection intervals are increased in 2- or 4-weekly increments to maintain stable visual and/or anatomic outcomes. If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly. No requirement for monitoring between injections. Based on the physician's judgement the schedule of monitoring visits may be more frequent than the injection visits. Treatment intervals greater than 4 months or shorter than 4 weeks have not been studied. *DMO* Treatment is initiated with 1 injection per month for 5 consecutive doses, followed by 1 injection every 2 months. Based on the physician's judgement of visual and/or anatomic outcomes, the treatment interval may be maintained at 2 months or individualised, such as with a treat-and-extend dosing regimen, where the treatment intervals are usually increased by 2-week increments to maintain stable visual and/or anatomic outcomes. There are limited data for treatment intervals longer than 4 months. If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly. Treatment intervals shorter than 4 weeks have not been studied. The schedule for monitoring should be determined by the treating physician. If visual and anatomic outcomes indicate that the patient is not benefiting from continued treatment, Eylea should be discontinued. *RVO* After the initial injection, treatment is given monthly. The interval between 2 doses should not be shorter than 1 month. If visual and anatomic outcomes indicate that the patient is not benefiting from continued treatment, Eylea should be discontinued. Monthly treatment continues until maximum visual acuity is achieved and/or there are no signs of disease activity. 3 or more consecutive, monthly injections may be needed. Treatment may then be continued with a treat-and-extend regimen with gradually increased treatment intervals to maintain stable visual and/or anatomic outcomes, however there are insufficient data to conclude on the length of these intervals.

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If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly. The monitoring and treatment schedule should be determined by the treating physician based on the individual patient's response. Monitoring for disease activity may include clinical examination, functional testing or imaging techniques (e.g. optical coherence tomography or fluorescein angiography). **Eylea 114.3 mg/mL:** Recommended dose is 8 mg aflibercept, equivalent to 0.07 mL. Treatment is initiated with 1 injection per month for 3 consecutive doses. *nAMD and DMO* Injection intervals may then be extended up to every 4 months based on physician's judgement of visual and/or anatomic outcomes. Subsequently, treatment intervals may be further extended up to 6 months, such as with a treat-and-extend (T&E) dosing regimen, while maintaining stable visual and/or anatomic outcomes. *RVO* Injection intervals may then be extended based on the physician's judgement of visual and/or anatomic outcomes. *All indications* For patients who have previously been treated with Eylea 40 mg/mL or other vascular endothelial growth factor (VEGF) inhibiting medicinal products and are switching to Eylea 114.3 mg/mL, the treatment regimen can differ from that used for treatment-naive patients. Treatment intervals should be determined based on visual and/or anatomic outcomes. In patients with stable visual and anatomic outcomes, previous treatment intervals can be maintained or extended after the first injection of Eylea 114.3 mg/mL, such as with a treat-and-extend dosing regimen. In patients with suboptimal visual and/or anatomic outcomes, treatment with Eylea 114.3 mg/mL may begin with 1 injection per month for up to 3 consecutive doses followed by adjustment of injection interval, such as with a treat-and-extend dosing regimen. Frequency of monitoring visits should be based on patient's status and physician's discretion. If visual and/or anatomic outcomes deteriorate, treatment interval should be shortened according to physician's discretion. Interval between 2 injections should not be shorter than 1 month. If visual and/or anatomic outcomes indicate that the patient is not benefiting from continued treatment, Eylea 114.3 mg/mL should be discontinued. *nAMD and DMO* Eylea at monthly doses of 8 mg has not been studied for more than 3 consecutive doses in the PULSAR (nAMD) and PHOTON (DMO) studies. Available data support the administration of more than 3 consecutive monthly doses for certain patients, however the data are currently limited. **Special populations:** ***Hepatic and/or renal impairment:*** No specific studies conducted. Available data do not suggest a need for dose adjustment. ***Elderly:*** Available data do not suggest a need for dose adjustment. Limited experience of Eylea 40 mg/mL in those with DMO over 75 years old. ***Paediatric:*** No relevant paediatric use in nAMD, DMO, RVO. **Contraindications:** Hypersensitivity to active substance or any excipient; active or suspected ocular or periocular infection; active severe intraocular inflammation. **Warnings & precautions:** Record name and batch number of administered product for traceability. Intravitreal injections have been associated with endophthalmitis, intraocular inflammation, retinal tear and detachment, and traumatic cataract. Aseptic injection technique essential. Instruct patients to report symptoms of any of the above-mentioned events without delay. Monitor patients during the week following injection to permit early treatment of infection. Increases in intraocular pressure (IOP) have been seen within 60 minutes of intravitreal injections, including Eylea; monitor and manage IOP and optic nerve head perfusion. Take special precautions in patients with poorly controlled glaucoma (do not inject if IOP ≥ 30 mmHg). Potential for immunogenicity as with other therapeutic proteins; instruct patients to report signs or symptoms of intraocular inflammation or hypersensitivity e.g. pain, photophobia or redness. Systemic adverse events including non-ocular haemorrhages and arterial thromboembolic events have been reported following intravitreal injection of VEGF inhibitors. Limited data on safety in patients with nAMD, DMO or RVO and history of stroke, transient ischaemic attacks or myocardial infarction within last 6 months. Exercise caution when treating such patients. Safety and efficacy of concurrent use in both eyes not studied; potential risk of increased systemic exposure and systemic adverse events. Limited data on concomitant use of Eylea with other anti-VEGF medicinal products (systemic or ocular).

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Caution in patients with risk factors for development of retinal pigment epithelial tears after anti-VEGF for nAMD including large and/or high pigment epithelial retinal detachment. Withhold treatment in patients with: decrease in best-corrected visual acuity of ≥30 letters compared with last assessment; rhegmatogenous retinal detachment; stage 3 or 4 macular holes; retinal break; subretinal haemorrhage in central fovea or ≥50% of total lesion area. Do not treat in 28 days prior to or following performed or planned intraocular surgery. Populations with limited data: diabetic patients with an HbA1c over 12%; proliferative diabetic retinopathy; active systemic infections; concurrent eye conditions such as retinal detachment or macular hole; diabetic patients with uncontrolled hypertension; ischaemic central and branch RVO (treatment not recommended in patients with clinical signs of irreversible ischaemic visual function loss) **(Eylea 40 mg/mL only)**; DMO due to type 1 diabetes **(Eylea 40 mg/mL only)**. Consider this lack of information when treating such patients. Contains polysorbate 20; polysorbates may cause allergic reactions. **Interactions:** No available data. **Fertility, pregnancy & lactation:** Do not use in pregnancy unless potential benefit outweighs potential risk to the foetus. Limited data in pregnant women. Animal studies have shown reproductive toxicity. Women of childbearing potential must use effective contraception during treatment and for at least 3 months **(Eylea 40 mg/mL)** or 4 months **(Eylea 114.3 mg/mL)** after last injection. Not recommended during breastfeeding as aflibercept may be excreted in human milk at low levels. Effects on breastfed infant unknown. No fertility data in humans. Animal studies with high systemic exposure indicate aflibercept can impair male and female fertility. **Effects on ability to drive and use machines:** Possible temporary visual disturbances. Patients should not drive or use machines until their visual function has recovered sufficiently. **Undesirable effects:** ***Common/very common:*** **Eylea 40 mg/mL & 114.3 mg/mL:** cataract, visual acuity reduced, conjunctival haemorrhage, IOP increased, vitreous detachment, vitreous floaters, retinal haemorrhage, vitreous haemorrhage, eye pain, punctate keratitis, corneal abrasion. **Eylea 114.3 mg/mL:** hypersensitivity. **Eylea 40 mg/mL:** retinal pigment epithelial tear (observed in nAMD studies only) and detachment, retinal degeneration, cataract (cortical, nuclear and subcapsular), corneal erosion, vision blurred, injection site pain, foreign body sensation in eyes, lacrimation increased, eyelid oedema, injection site haemorrhage, conjunctival hyperaemia, ocular hyperaemia. **Serious:** *cf. CI/W&P* **Eylea 40 mg/mL & 114.3 mg/mL:** cataract, IOP increased, vitreous haemorrhage, retinal detachment, blindness, scleritis. **Eylea 114.3 mg/mL:** retinal haemorrhage, cataract subcapsular, retinal tear, cataract nuclear. **Eylea 40 mg/mL:** endophthalmitis, cataract traumatic, vitreous detachment, isolated cases of severe anaphylactic/anaphylactoid reactions. The following adverse reactions of Eylea 40 mg/mL are also considered expected with Eylea 114.3 mg/mL: abnormal sensation in eye, corneal epithelium defect, anterior chamber flare, traumatic cataract, hypopyon, severe anaphylactic/anaphylactoid reactions. Increased incidence of conjunctival haemorrhage in patients receiving anti-thrombotic agents observed in Eylea 40 mg/mL nAMD phase III studies. Incidence comparable between ranibizumab and Eylea. Theoretical risk of arterial thromboembolic events (ATEs) including stroke and myocardial infarction following intravitreal use of VEGF inhibitors. A low incidence rate of ATEs was observed in the Eylea clinical studies. Across indications, no notable difference in ATEs observed between groups treated with Eylea 114.3 mg/mL or Eylea 40 mg/mL and respective comparator groups. Consult SmPCs in relation to other adverse reactions. **Overdose:** Monitor IOP and treat if required. **Incompatibilities:** Do not mix with other medicinal products. **Special Precautions for Storage:** Store in a refrigerator (2°C to 8°C). Do not freeze. Keep PFS in its blister and in the outer carton to protect from light. Prior to usage, the unopened blister may be stored outside the refrigerator below 25°C for up to 24 hours. **Legal Category:** POM. **Package Quantities & Basic NHS Costs:** Eylea 40 mg/mL: £816.00. Eylea 114.3 mg/mL: £998.00. **MA Numbers:** PLGB 00010/0676 & PLGB 00010/0758 **Further information available from:** Bayer plc, 400 South Oak Way, Reading RG2 6AD, United Kingdom. Telephone: 0118 206 3000.

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